IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Saxinger

Art Unit: 1648

Application No. 10/084,813

Examiner: Jeffrey S. Parkin

Filed: February 27, 2002

For: POLYPEPTIDES THAT BIND HIV gp120 AND RELATED NUCLEIC ACIDS, ANTIBODIES, COMPOSITIONS, AND METHODS OF USE

DECLARATION UNDER 37 C.F.R. § 1.132 OF CARL SAXINGER, PH.D.

I, Carl Saxinger, Ph.D. do hereby declare that:

1. I am the sole inventor of the subject matter disclosed and claimed in the instant application. I have been actively engaged in research since a time prior to the filing of the instant application, and I am familiar with the general knowledge that was available to the person of ordinary skill in the art at that time.

2. The pending claims of the instant application are directed to a polypeptide that comprises an amino acid sequence selected from the group consisting of SEQ ID NOS: 12-15 with up to 6 conservative or neutral amino acid substitutions. The claims require that the polypeptide bind with HIV gp120 under physiological conditions.

3. The person of ordinary skill in the art at the time the instant application was filed understood a "conservative" or "neutral" amino acid substitution to mean the substitution of a given amino acid residue for a different amino acid residue having similar physical/chemical properties. It was further understood by a person of ordinary skill in the art at that time that a "conservative" or "neutral" amino acid substitution was not likely to abolish the function of a given amino acid sequence.

4. The person of ordinary skill in the art at the time the instant application was filed was aware of the physical and chemical properties of the various amino

acids available at that time, including the physical and chemical properties of each of the amino acid residues of the sequences recited in the pending claims. Given such knowledge, it was well within the skill of such a person at that time to predict and determine whether a given amino acid substitution would be conservative or neutral. Furthermore, the instant application provides specific guidance on this point (e.g., at page 7, line 12 – page 8, line 11).

5. The person of ordinary skill in the art at the time the instant application was filed understood that an amino acid sequence is a polymer or chain of amino acid residues, each with specific physical and chemical properties. Such person also was aware that the function of the amino acid sequence (e.g., binding properties) depends upon the physical and chemical properties of the individual amino acid residues.

6. Because a conservative or neutral amino acid substitution is a substitution of one amino acid for another having similar chemical or physical properties, one of ordinary skill in the art at the time the application was filed understood that an amino acid sequence containing one or more conservative or neutral amino acid substitutions is likely to retain physical and chemical properties similar to the original (e.g., unsubstituted) amino acid sequence. Such a person at that time also understood that an amino acid sequence containing conservative or neutral amino acid substitutions was, therefore, likely to retain the function of the original (e.g., unsubstituted) amino acid sequence, at least to some degree.

7. The instant application provides additional guidance as to the correlation between the structure and function of the claimed polypeptides. For instance, Example 1 illustrates that SEQ ID NOS: 12-15 bind with high affinity to HIV gp120 (e.g., in Example 1, SEQ ID NOS: 54 and 55 correspond (in part) to SEQ ID NO: 12; SEQ ID NO: 77 corresponds to SEQ ID NO: 13; SEQ ID NOS: 93 and 94 correspond (in part) to SEQ ID NO: 14; and SEQ ID NO: 105 corresponds to SEQ ID NO: 15).

8. Example 1 further illustrates that amino acid sequences comprising only a portion of SEQ ID NOS: 12-15 also bind to HIV gp120 with relatively high affinity (e.g., in Example 1, SEQ ID NOS: 53 and 56 contain part of SEQ ID NO: 12; SEQ ID NOS: 73-76 contain part of SEQ ID NO: 13; SEQ ID NOS: 92 and 95 contain part of SEQ ID NO: 14; and SEQ ID NOS: 102-104 contain part of SEQ ID NO: 15), but that other amino acid sequences that comprise a different portion of SEQ

ID NOS: 12-15 do not share the same binding affinity with HIV gp120 (e.g., in Example 1, SEQ ID NOS: 50-52 and 57-59 contain part of SEQ ID NO: 12; SEQ ID NOS: 78-81 contain part of SEQ ID NO: 13; SEQ ID NOS: 89-91 and 96-98 contain part of SEQ ID NO: 14; and SEQ ID NOS: 101 and 106-109 contain part of SEQ ID NO: 15).

9. Given the amino acid sequences recited in the pending claims, and in view of the general knowledge in the art and the disclosures of the specification as summarized herein, a person of ordinary skill in the art at the time the instant application was filed could immediately have recognized that conservative or neutral amino acid substitutions could be made that would likely preserve the function of the amino acid sequence, at least to some degree. Furthermore, such a person could immediately have ascertained other amino acid sequences based on those recited in the claims with up to six conservative or neutral amino acid substitutions.

10. I hereby each declare that all statements made herein of our own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 7/31/05

Carl Saxinger, Ph.D.